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MAR 4 2002

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
7992 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Densmore

Date: December 20, 2001

807.92(a)(2)

Trade Name: SONOReal 3D System

Common Name: Digital Ultrasound Image Analysis System

Classification Name(s): System, Imaging, Pulsed Echo, Ultrasonic

Classification Number: 90IYO

807.92(a)(3)

Predicate Device(s)

EchoTech	3D FreeScan	K980308
BioMediCom	Baby Face	K994385
BioMediCom	SonoReal 3D	K012084

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
SONOReal 3D System - Addition of Measurement Function
BioMediCom, Ltd.

807.92(a)(5)

Intended Use(s)

Intended to be used by or under the direction of a physician and in conjunction with a standard ultrasound system to provide 3D and Multi-planar clinical imaging in fetal and gynecological applications. *SONOReal™* is intended to visualize features that the user may wish to examine more closely in routine 2D ultrasound diagnostic imaging examinations. The user is offered the capability to perform linear, area and volumetric measurements of the subject being scanned. *SONOReal™* does not provide any diagnostic interpretations.

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510(k) Summary
SONOReal 3D System - Addition of Measurement Function
BioMediCom, Ltd.

Comparison Chart for Substantial Equivalence

	EchoTech 3D FreeScan K980308	BioMediCom SONOReal 3D System K994385 Addition of Measurement Function
Basic Function	Adds 3D imaging capability to commercial 2D ultrasound imaging systems	Adds 3D imaging capability to commercial 2D ultrasound imaging systems
Hardware	Pentium II 400 MHz	Pentium III 833 MHz
	Frame Grabber (VHS/S-VHS Input)	Frame Grabber (VHS/S-VHS Input)
	Video out	Video out
	Foot pedal	Handheld controller
Software features	Volume data acquisition w/frame grabbing of video data b/w while using an Electro magnetic sensor system	Volume data acquisition w/frame grabbing of video data b/w while using a Gyroscopic sensor system
	Conditioning & transformation of the acquired data into a Cartesian volume	Conditioning & transformation of the acquired data into a Cartesian volume
	Surface rendering	Surface rendering
	Segmentation of structures from 3D data	Segmentation of structures from 3D data
	Quantitative evaluation	No
	Measurements & calculations	Measurement and calculations Via this submission
Indications for Use	Gynecology/OB, radiology, neurology, gastroenterology, urology, surgery, orthopedics, and oncology	Fetal/ Gynecology

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2002

BioMediCom, Ltd.
% Ms. Colleen Densmore
Official Correspondent
The Anson Group
7992 Castleway Drive
INDIANAPOLIS IN 46205

Re: K020068
Trade/Device Name: SONOReal™ 3D System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: January 2, 2002
Received: January 9, 2002

Dear Ms. Densmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Applicant: BioMediCom, Ltd.

510(k) Number (if known): K020068

Device Name: SonoReal 3D

Indications For Use:

Intended to be used by or under the direction of a physician and in conjunction with a standard ultrasound system to provide 3D and Multi-planar clinical imaging in fetal and gynecological applications. *SONOReal™* is intended to visualize features that the user may wish to examine more closely in routine 2D ultrasound diagnostic imaging examinations. The user is offered the capability to perform linear, area and volumetric measurements of the subject being scanned. *SONOReal™* does not provide any diagnostic interpretations.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** Over The Counter _____

(Per 21 CFR, 801.109)

(Optional Format 1-2-96)

David L. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020068